DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 6, 2015

Huizhou Foryou Medical Devices Company, Ltd.
% Mr. Charles Shen
Manton Business and Technology Services
853 Dorchester Lane, Unit-B
Pennington, New Jersey 08534

Re: K141619
Trade/Device Name: Luofucon Silver Foam Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: March 20, 2015
Received: March 24, 2015

Dear Mr. Shen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141619

Device Name
Luofucon Silver Foam Dressing

Indications for Use *(Describe)*
The Luofucon Silver Foam Dressing is indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are:

- Ulcers (venous, arterial, diabetic)
- Pressure Sores
- Donor Sites
- Surgical Incisions
- Surgical Excisions
- Burns (1st and 2nd degree)

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary:

This summary of 510k safety and effectiveness information is being submitted in accordance with the requirements of 21CFR 807.92

Submitter & Foreign Manufacture Identification

Huizhou Foryou Medical Devices Co., Ltd.
No.1, Shangxia North Road, Dongjiang Hi-Tech Industry Park,
Huizhou, Guangdong Province, China
Tel: (086) 0752-5302188
Submitter's FDA Registration Number：3007735241

US Agent and Contact Person

Charles Shen
Manton Business and Technology Services
853 Dorchester Ln, Unit-B
Pennington, NJ 08534
Tel: 608-217-9358
Email: cyshen@aol.com

Date of Summary: March 31, 2015

Device Name:	
Trade Name:	Luofucon Silver Foam Dressing
Common Name:	Silver Foam Dressing
Classification Name:	Dressing, wound, Drug
Product Code:	FRO
Regulation Number:	Unclassified
Review Panel:	General & Plastic Surgery

Predicate Device Information:

(1) K110062, "MediPlus-Foam AG Dressings, MediPlus-ComfortFoam AG Dressings, MediPlus-SuperFoam AG Dressings", manufactured by "MediPurpose, Pte. Ltd." located in Norcross, GA

Device description:

Luofucon Silver Foam Dressing is a sterile, single-use dressing composed of polyurethane and silver particles, which absorbs wound exudate and releases silver ions in the presence of wound fluid. It also assists in maintaining a moist environment for optimal wound healing, and allows intact removal.

The polyurethane material consists of metallic silver that provides effective protection of the dressing material (not wound) against bacterial contamination. The silver is a preservative that protects the dressing material (not wound) from a broad spectrum of bacteria over three days, based on in vitro laboratory testing.

All dressings are sterilized and sold directly to users after sterilization by EtO using conditions validated following ISO 11135-1: 2007.

The silver foam dressing in this submission consists of four variants:

The basic model, dressing without backing, is a sterile highly absorbing open cell hydrophilic wound dressing composed of a thick soft, smooth, elastic and breathable Polyurethane foam encapsulated with silver particles as an antimicrobial barrier. The product line is available in different sizes.

A second variant, non adhesive PU backing variant, has a two-layered structure: a thick layer of soft, smooth elastic and breathable Polyurethane foam encapsulated with silver particles, and a thin layer (0.025±0.005 mm thick) of non porous breathable Polyurethane film (backing film) laminated on the outer side (non-wound contacting side) of the thick layer. The thin backing has the same area as the thick soft Polyurethane layer and is for cosmetic purpose. The product line is available in different sizes.

A third adhesive variant, bordered PU adhesive backing variant, has a three-layered structure. A thin Polyurethane film layer (0.04±0.005 mm thick), served as backing, is laminated to the top of the thick layer of soft, breathable, and silver encapsulated Polyurethane foam. Then on top of second layer is a large thin film of Poly(ethylene terephthalate) (PET) (0.04±0.005 mm thick) with pressure-sensitive adhesive to secure the dressing on patient skin surface. The backing polyurethane layer and PET layer are waterproof and semi permeable, and are used to secure the foam onto patient skin. The product line is available in different sizes.

A fourth adhesive variant, bordered non-woven adhesive backing variant, is similar to the third variant and also has a three layered structure. A thin Polyurethane film layer (0.04±0.005 mm thick), served as backing, is laminated to the top of the thick layer of soft, breathable, and silver encapsulated Polyurethane foam. Then on top of second layer is a large thin film of non-woven material (0.28±0.02 mm thick) with pressure-sensitive adhesive to secure the dressing on patient skin surface. The non woven material is made from viscose rayon fiber and poly(ethylene terephthalate) fiber. The backing polyurethane layer and non woven layer are waterproof and semi permeable, and are used to secure the foam onto patient skin. The product line is available in different sizes.

The dressing has white appearance and is available in the form of pad and in different sizes packaged in pouches. All dressings have the exactly the same material, chemical, and physical properties and are different only in size and backing.

Product Information:

Antibacterial Agent:	Silver Particles
Active Against Pathogens:	Gram positive and Gram negative bacteria
Spectrum of Activity:	Board spectrum antibacterial effect for Gram positive and Gram negative bacteria
Concentration on the device:	Each dressing contains 3±1 μg/cm^3 silver particles

Silver serves as a preservative against bacterial growth in the dressing material

Indication for Use:

The Luofucon Silver Foam Dressing is indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are:

- Ulcers (venous, arterial, diabetic)
- Pressure Sores
- Donor Sites
- Surgical Incisions
- Surgical Excisions
- Burns (1st and 2nd degree)

Comparison to Predicate Devices

Luofucon Silver Foam Dressing is compared with the following Predicate Devices in terms of intended use, design, material, specifications, and performance.

1) K110062, "MediPlus-Foam AG Dressings, MediPlus-ComfortFoam AG Dressings, MediPlus-SuperFoam AG Dressings", manufactured by "MediPurpose, Pte. Ltd." located in Norcross, GA

The following table shows similarities and differences of use, design, material, and processing methods between our device and the predicate devices.

Table 5.1: Comparison of Intended Use, Design, and Material

Description	Our Device	Predicate Device 1 (K110062)
Indication for Use	The Luofucon Silver Foam Dressing is indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are: • Ulcers (venous, arterial, diabetic) • Pressure Sores • Donor Sites • Surgical Incisions • Surgical Excisions • Burns (1st and 2nd degree)	The MediPlus-Foam AG, MediPlus-ComfortFoam AG, and MediPlus-SuperFoam AG Dressings are indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are: • Ulcers (venous, arterial, diabetic) • Pressure Sores • Donor Sites • Surgical Incisions • Surgical Excisions • Burns (1st and 2nd degree)
Prescription/ OTC	Prescription	Same
Mechanism	Silver for antibacterial preservative effect; polyurethane foam for exudate absorption and wound care	Same
Design/ Material	Polyurethane foam and silver	Same
Antibacterial Duration	Three days	5-7 days
Single Use	Yes	Yes
Sterile	Sterile	Sterile

Both Luofucon Silver Foam Dressing and its predicate device (K110062) utilize silver as the antibacterial agent, and utilize polyurethane foam for the exudate absorption and wound management.

One minor difference between our device and predicate device is that predicate device uses multi-layered polyurethane structure, and our device has either single layered or double layered structure. This small difference does not impact the safety and efficacy of our devices because both devices use the silver particle as the antibacterial preservative agent and utilize polyurethane foam for the exudate absorption and wound management.

The other minor difference is the silver content. The subject device contains less silver than the predicate device, and is at the safe level based on toxicology assessment, therefore does not raise new safety concerns.

Therefore, Luofucon Silver Foam Dressing and its predicate devices are made from similar materials, utilize same antibacterial mechanism, and have similar intended use.

Table 5.2 shows similarities and differences of the performance between our device and the predicate devices.

Table 5.2: Comparison of Biocompatibility and Performance Testing

Description	Our Device	Predicate Device (K110062)
Cytotoxicity	No Toxic Effect (ISO10993-5)	Biocompatible
Skin Irritation and Sensitization	No Effect (ISO 10993-10)	
Systematic Toxicity	No Effect (ISO 10993-11)	
Antibacterial Activity	Broad spectrum protection	Broad spectrum protection
Antibacterial Duration	Three days	5-7 days

Luofucon Silver Foam Dressing meets biocompatibility requirements per ISO 10993-5, ISO 10993-10, and ISO 10993-11. It's physical and performance meets the requirements of its pre-defined acceptance criteria and intended uses. All dressings are sterilized and sold directly to users after sterilization by EtO using conditions validated following ISO 11135-1: 2007.

To support broad spectrum antibacterial preservative effectiveness of the Silver Foam Dressing, we evaluated a total of six (three Gram positive and three Gram negative) bacteria. Luofucon Silver Foam Dressing demonstrated a 4 log reduction in all six bacteria for three days in *in vitro* testing.

Therefore, the performance results are comparable to the predicate devices when the dressings are used for antibacterial purpose for three days. The product is safe and effective for its intended use.

Substantial Equivalent Statement

Based on the comparison of intended use, design, materials, and performance, our Luofucon Silver Foam Dressing is substantial equivalent to its predicate devices.